Guidance for Beef Grinders to Better Protect Public Health

Guidance for Minimizing Impact Associated with a Food Safety Hazard in Raw Ground Meat and Other FSIS Regulated Products

Based upon recent product recalls involving *Escherichia coli (E. coli)* O157:H7, FSIS has concluded that effective guidance can help grinding operations better protect public health.

The guidance provided in this document is premised on three main points:

- First, grinders should structure their operations in a manner that takes into account the safety of their raw materials and their potential product safety responsibilities through to the end user.

- Second, grinders should realize that they are in an excellent position to implement process and distribution controls that reduce public health concerns associated with ground beef contaminated with *E. coli* O157:H7.

- Third, there must be an emphasis throughout the production and distribution chain on maintaining the records that are necessary to identify, trace, and retrieve from commerce any ground beef that may pose a threat to public health.

Grinding operations (which traditionally buy raw materials from one or more sources and sell the processed products to others) have a primary responsibility and unique opportunity to specify purchase requirements related to incoming raw materials, to process raw materials under processing and recordkeeping controls designed to ensure the safety and traceability of their products, and to distribute products to destinations in a manner such that products can be effectively recalled if food safety hazards are identified. Putting aside any legal considerations, it is essential that grinding operators assume that they may be responsible for their products until the products' end use. This is especially true for grinding operators who produce products in retail-ready packages. This guidance material, through several guiding principles and associated detailed explanations and recommendations, is intended to identify how grinding operations can reduce public health risk.

Processing operations are presently required to have SSOP's (Sanitation Standard Operating Procedures) and a few are already required to have functional HACCP (Hazard Analysis Critical Control Points) systems. This guidance material is specifically designed to augment these activities, especially the development and operation of a HACCP plan[1, 2]. Grinding operations not already required to have HACCP plans are encouraged to develop and implement their

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[1] USDA, FSIS (1997) Generic HACCP Model for Raw, Ground Meat and Poultry Products, HACCP-3.

[2] USDA, FSIS (1997) Generic HACCP Model for Beef Slaughter, HACCP-13.

Food Safety and Inspection Service
March 1998
Available for Public Comment

HACCP plans earlier than required as soon as possible[3]. Although this guidance material highlights issues associated with ground beef, the guidance can be applied to most other raw products. This guide is not intended to be prescriptive, in a regulatory sense, but rather offers examples of opportunities to improve food safety through purchase requirements, increased process control, and recordkeeping.

Records that facilitate trace back and trace forward are essential whenever there is an outbreak of foodborne illness. Although grinding operators may not have access to records of the farm sources of their raw material, or records maintained by the plants that slaughter, dress, and bone their raw materials, they are advised to purchase raw materials from suppliers that maintain such records. In addition, they are advised to keep records regarding the disposition of their products to enable tracing their products forward to consumers and back to suppliers. In instances where grinders do not control their products through distribution and retail sale, the chain of records necessary to trace products that raise a public health concern should not be broken. Intermediate handlers, such as distributors and wholesalers, need to assume responsibility for keeping adequate records regarding the disposition of ground beef products that pass through their hands. The Federal Meat Inspection Act (FMIA) requires that every person, firm, or corporation engaged in the buying or selling of meat food products must maintain records that fully and correctly disclose all transactions in its business subject to the FMIA (21 USC 642). The recordkeeping requirements are set out in Title 9, Code of Federal Regulations, Section 320 (9 CFR 320). Grinders are advised to impress upon all intermediate handlers of their products the importance of records that will facilitate the efficient retrieval from consumers of ground beef products that are a public health concern.

The pathogen *E. coli* O157:H7 is of particular concern to grinding operations because it is considered an adulterant in ground beef (Taylor, 1994; Texas Food Industry Association v. Espy)[4], and because it produces severe and sometimes fatal consequences at a very low infectious dose. Buchanan and Doyle (1997)[5] emphasized that "HACCP plans that do not include a lethal step that kills pathogens are more complex, since the focus is on risk reduction instead of risk elimination." At present, applying a lethal step such as heat processing or integrated lethality using fermentation or pH is the only approved method of making food harboring *E. coli* O157:H7 safe for consumption. Results from microbiological testing can provide only a limited measure of assurance that this pathogen is not present. Total reliance upon

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[3] Federal Register: January 30, 1998 (Volume 63, Number 20) p. 4622

[4] Taylor, M. (1994) Change and Opportunity: Harnessing Innovation To Improve The Safety of the Food Supply. Speech given at the American Meat Institute Annual Convention, San Francisco, California, September 29, 1994.

Texas Food Industry Association v. Espy, 870F.supp.143,149,(W.D. Tex.1994)

[5] Buchanan, R. L., and Doyle, M. P. (1997) Foodborne disease significance of *Escherichia coli* O157:H7 and other enterohemorrhagic *E. coli*. Food Tech. 51(10): 69-76.

sampling is inadequate because *E. coli* O157:H7, if present, is present sporadically and at extremely low levels. Therefore, microbiological testing should be used in combination with strict process controls in order to reduce, as much as possible, the likelihood that the pathogen is present in the finished product. The agency issued on February 1, 1998, FSIS Directive 10,010.1 Microbiological Testing Program For *Escherichia coli* O157:H7 in Raw Ground Beef, which delineates the conditions for testing of the pathogen.

This guide consists of two sections: Section I., Guiding Principles; and Section II., Suggested Procedures For Grinding Operations. This material will be continually updated and made available through the FSIS Internet Web Site located at http://www.usda.gov/fsis. Copies of this Guidance for Beef Grinders to Better Protect Public Health may also be requested by fax or mail from FSIS Public Outreach, 202-720-9063; Room 1180 South Building, Washington D.C. 20250. Comments regarding this guide should be directed to William J. Hudnall, at 202-205-0495, and fax at 202-401-1760.

Section I. Guiding Principles:
These guiding principles are supplemented with suggested procedures in Section II.

A. Grinders should determine the specifications for microbial safety that are necessary to ensure that their specific products will be safe and should only accept starting materials and ingredients that meet their specifications. In developing such specifications, grinders should consider the intended use for the starting materials and ingredients and what, if any, pathogen reduction actions by their suppliers would be beneficial.

B. Grinders should keep abreast of new technologies and interventions that could be introduced into their processes to help prevent adulterated products or to identify product that is adulterated before it enters commerce.

C. Grinders should develop and implement processes and packaging procedures to maintain or improve the microbial integrity of their starting materials in order to ensure that they produce safe consumer products.

D. Grinders should implement controls to identify and segregate for special handling, products that pose a greater risk of being adulterated. Alternate outlets, such as diversion to FSIS inspected or state-inspected processors that employ a bacterial kill-step (such as cooking), should be acquired for such products.

E. Grinders should develop and implement rework, carry-over, and lot designation procedures that reflect an acceptable degree of product exposure (i.e., economic risk) in the event that a health risk is identified which requires recalling any product that is suspected of presenting a potential hazard to the public.

F. In cooperation with their customers, grinders should develop and implement handling and distribution procedures that will not compromise the safety of their ground products once those products leave their grinding establishments.

G. Grinders should develop a system of records, which fits into a farm-to-table continuum that will facilitate trace back to the suppliers and trace forward to the distributors in the event that a public health risk is identified.

H. Grinders should consider both the intended use of their product (hotel, restaurant, institution, or home setting) and the most vulnerable potential user; and should provide information and education aimed at minimizing the potential for foodborne illness at the level of the ultimate consumer. Moreover, such information and education can help to assure consumers that product found to have *E. coli* O157:H7 can be made safe by thorough cooking. Steps are

available to ensure that product presumed or known to have *E. coli* O157:H7 is made safe as opposed to destroying it.

Section II. Suggested Procedures for the Guiding Principles

Receiving Meat (Guiding Principles A and B)

- Develop purchase specifications to ensure receipt of safe and wholesome incoming raw materials. Purchase specifications should take the end use of the product into consideration. For example, purchase specifications for raw materials for processing products with potentially high risk end use, such as raw patties, should include either:

    1) establishing in-house microbial specifications, or
    2) requiring suppliers to have HACCP plans with critical control points (CCP's) that address pathogen intervention or anti-microbial programs, such as hot water rinses, steam pasteurization, or irradiation.*

- Require suppliers to maintain records that facilitate traceback.

    **The Food and Drug Administration approved the irradiation of meat in December 1997. FSIS is currently working to develop rulemaking to implement irradiation of meat. Grinding operators should be aware of new technologies such as steam pasteurization and other intervention methods applied to carcasses to reduce the number of microbial contaminants, including pathogens.*

- Examine conditions of transport, including temperature inside transport vehicles and of meat, as well as duration of transport.

- Examine and record condition of raw material:

    1) Note and document age and temperature of the meat, both refrigerated and frozen.
    2) Conduct organoleptic examination (appearance, smell, any defects or abnormalities).
    3) Check integrity of immediate container, protective covering, or other packaging materials used.
    4) Document type of raw materials [e.g., trimmings, cheek meat, finely textured, product from Advanced Meat Recovery (AMR) systems, and other comminuted products which undergo additional handling and processing].
    5) Verify that all units are appropriately marked or coded for trace back purposes.

- Affix grinding operation's code for tracking purposes.

- Identify and separate incoming material according to the potential risk of the product's end use. Small mass products such as raw beef patties are "high risk" because they are thin, are cooked for a short time, are preferred not fully cooked by some consumers, and the internal temperature is not easily obtained. Large mass products such as meat loaf or chili are "low risk" because they are more dense and are cooked evenly for a longer time. Ready-to-eat (RTE) products such as cooked beef patties are "low risk" because these have undergone a processing step lethal to pathogens.

Storage of Raw Material (Guiding Principle C)

- Identify storage schedule for incoming material.
- Determine which units will be refrigerated or frozen, and for how long.
- Record specific locations, times, dates, and temperature of storage.
- Monitor and record temperature of meat during storage.
- If material is to be thawed, monitor, and record time and temperature of thawing.

Grinding Process including weighing, coarse grinding, blending, mixing, final grinding, and patty-forming (Guiding Principles C, D, E)

- Observe and record pre-operational SSOP conformance including those for equipment, floor, ceilings, walls, and employees. Adopt testing (e.g., microbial, ATP bioluminescence) to measure effectiveness of SSOP.
- Assign lot numbers. All lots produced between cleanups would be implicated in any public health issue (e.g., recall) unless specific circumstances allow the problem to be further isolated to a subset of the plant's production between cleanups.
- Monitor temperature of the meat and the processing room during the whole operation.
- Separate processing of meat by risk categories. Separation can be by processing lines, lots, shifts, or production day. Large processing plants may be able to use different processing lines for various categories. In small plants, the categories can be separated by shifts or lots, in which case, processing of **"**low risk" raw materials should always precede "high risk" raw materials.

Separation of raw materials into these two categories will prevent possible cross contamination among meat with different handling history.

- Develop a rework tracking system

    1) Estimate the amount of meat for the production shift or day, so that the amount of carry-over meat is minimal, or there is no rework at the end of the day.
    2) If rework is unavoidable, use only rework meat from the immediately preceding lot or shift, or not more than 24-hours old.
    3) Include rework with "high risk" meat and process at the last shift or the end of the production day.
    4) Develop a recording system for rework that includes the time, quantity, area or processing step it was collected from, and the original lot or batch number/code.

- Divert "high risk" meat to:

    1) Ready-to-Eat (RTE) product such as fully cooked beef patties. RTE processing incorporates a kill-step such as heat processing, or cooking which eliminates any pathogen including *E. coli* O157:H7.
    2) Large mass products such as meat for meat loaf or chili. This diversion will help ensure adequate heat processing of the product at the consumers' end, because these large mass products are more fully and evenly cooked than thin meat patties.

    Diverting "high risk" meat to RTE or large mass product processing is an in-house method to reduce the risk of foodborne illness because these diverted products are in general, adequately cooked before consumption. In diversifying, grinders that have no facilities for processing RTE products need outlets for their "high risk" products. Grinders should obtain a list of FSIS-inspected and state-inspected establishments that can process ground beef RTE products.

- Monitor the time and temperature of finished products; e.g., freezing beef patties.

- Test for *E. coli* O157:H7 at any point during the grinding operation. To reduce the risk of a recall, hold the product until the test results confirm that none has been detected.

    Testing may help to determine whether to divert to other products. Because of the low incidence of E. coli O157:H7 in meat, testing is not a guarantee of the absolute absence of the pathogen, and the amount and frequency of sampling from different volumes of meat being processed will vary. The point of sampling, whether raw material or the finished

product, will also vary, depending on the condition of the raw material, whether there was previous testing done, the system of controls in the plant, and the type of finished product.

Packaging, Cooling, and Storage (Guiding Principle C)

- Monitor temperature or frozen condition of finished product during the packing operation.
- Use only clean food grade immediate container liners.
- Monitor finished product package integrity (seal, durability).
- Monitor and record the temperature of the freezer and the meat during storage.
- Include production code and sell-by-date on package label, in addition to the required handling statement and safe handling instructions.
- Install a time-temperature indicator on the package to indicate adequate temperature of storage, distribution, and display (in grocery and other retail establishments).

Shipping, Handling, and Distribution (Guiding Principle F)

- Develop recommendations for distributors concerning the safe handling, distribution, and coding of the finished products.
- Separate and divert to "high risk" any product that was returned to the plant after having left the plant and been out of the control of the plant.
- Develop an in-house recall plan to test the efficiency of the plant's recording or coding system. Scheduling product recovery drills (mock recalls) can determine the effectiveness of the recall plan.

Recordkeeping System (Guiding Principle G)

- Develop a recording or coding system so that each shipping container or a retail-ready package of ground beef has trace back and trace forward codes.

A coding system could be as simple as indicating the shift, date and production line. For example, a code of 1/020898/2 would mean produced on 'first shift of February 8, 1998, line 2'. Corresponding records of all incoming products used on February 8, by shift and line, would enable full trace back to sources.

- These codes should facilitate tracking or trace back to the farm source, slaughter plant, and boning plant; a determination whether the meat was reconditioned, had intervention treatment, or had rework meat added to it; and a determination of the dates of slaughter and fabrication, lot number, storage, and transport records.

- Encourage primary and secondary distributors to maintain a record of the companies to which they supply finished products. This will ensure effective trace forward of all products, if the need arises.

  Thorough recordkeeping, including tracing back and forward, will facilitate recall efforts. This will make possible rapid identification of sources of microbial contamination leading to containment of any product that could result in foodborne illness and public health implications. This will minimize the economic impact of recalls on affected plants, by narrowing down implicated products to a certain lot or production code.

Education (Guiding principle H)

- Grinding plants that have developed programs to educate their employees, handlers, and consumers of the risks of foodborne illness associated with the production of ground beef products should continually monitor and update their programs.

- Grinding plants without such programs should develop training and educational programs for employees, distributors, food handlers, and consumers on the microbiological risks that may be associated with ground beef products, and on measures to prevent foodborne illness.

- Although safe handling instructions are currently required for raw meat distributed to consumers, grinding plants should include more effective handling information on products distributed between establishments.

- Grinding plants should include more descriptive cooking instructions on their products which reflect the necessary safety guidance for the targeted purchaser (i.e., product distributed to institutions with special populations of elderly, young, or immuno-compromised people should include more rigorous cooking and handling instructions than provided for the general population).

A list of materials that may aid grinding plants in training and education is being assembled. It will be announced when available. Also, information about materials available from the HACCP Database of Training Programs and Resources Database and the USDA/FDA Foodborne Illness Education Information Center is available on the World Wide Web at www.nal.usda.gov/fnic/foodborne.htm. Other consumer publications and educational

information are available on the FSIS Web site at (http://www.usda.gov/fsis) under News and Information.

PROCESS FLOW DIAGRAM FOR RAW GROUND BEEF PROCESSING AND RECOMMENDATIONS

Receiving Meat

- Require purchase specifications
- Examine condition of transport
- Examine condition of raw material
- Identify and group raw material
- Code accepted raw materials

Storage of Meat

- Develop storage schedule
- Monitor and record time, temperature and location of storage

Grinding Process (weighing, coarse grinding, blending, mixing, final grinding)

- Pre-operational SSOP
- Assign lot numbers
- Monitor and record temperature of meat and processing room
- Separate processing of meat groups according to product's end use
- Develop tracking system for rework meat
- Divert "high risk" meat to other products
- Monitor and record temperature of finished products, e.g., freezing of patties
- Test for *E. coli* O157:H7/ other pathogens

Packaging, Cooling, and Storage

- Monitor time and temperature of product during packing and storage
- Test package integrity, immediate container lining
- Assign production code and sell-by-date on package label
- Install time-temperature indicator on packages

Shipping, Handling, and Distribution

- Maintain recordkeeping for primary and secondary distributors
- Develop a disposition plan for returned products
- Develop recommendations from grinders to distributors on the handling of products
- Develop and institute an in-house recall plan, product recovery drills (mock recalls)

Food Safety and Inspection Service
March 1998
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